EU Quality Management Certificate

This is to certify that the company

PICTERUS AS

Kjøpmannsgata 61
7011 Trondheim
Norway

SRN: NO-MF-000002136

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	549089 MDR2017Q
Certificate ID	1000231881
Effective date	2025-04-14
Expiry date	2026-10-27
Frankfurt am Main,	2025-04-14

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Annex to EU Quality Management Certificate
SRN of Manufacturer: NO-MF-000002136
Certificate ID: 1000231881

Device categories and variants covered by this certificate:

Device category:	MDA 0315 - Software
Product name:	Picterus Jaundice Pro
Risk classification:	IIa
Basic-UDI-DI:	707308701PicterusL6
Intended purpose:	The Picterus® Jaundice Pro is intended to assist in screening and follow up of neonatal jaundice.

Examinations and tests performed:
549089_A208431MED_420_11e_Report_MED_2021-10-18 dated 2021-10-22
549089_A209952MED_01 dated 2022-03-05
549089_Report-Technical-File-Review_Picterus-Jaundice-Pro_2 dated 2021-07-16
549089_A210785MED_01 dated 2022-10-23
549089_A215537MED_01 dated 2024-11-16
549089_A214835MED dated 2025-03-21

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-17	170779050	Extension of the indication of the app (user group)
02	2022-12-02	170781888	New certificate template and change of address
03	2024-07-24	1000189527	Description of intended purpose of certificate adjusted
04	2024-11-25	1000206191	Change of the intended use to cover all skin and addition of a new algorithm